APR 1 6 2002

Summary of Safety and Effectiveness Information *Premarket Notification, Section 510(k)*	TECHNOLOGY DELIVERY SYSTEMS, INC. SEPTEMBER 6, 2001

Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

K013300 1/3

1. ***Device Name:***

Trade Name: ***MaxiFlex Fiberoptic Energy Delivery System***
Common Name(s): Surgical Laser System
Classification Name(s): Laser, Surgical

2. ***Establishment Name & Registration Number:***

Name: Technology Delivery Systems, Inc.
Number: applied/pending

3. ***Classification(s):***

§ 878.4810 Laser surgical instrument for use in general and plastic surgery and in dermatology. (a) Identification. (1) A carbon dioxide laser for use in general surgery and in dermatology is a laser device intended to cut, destroy, or remove tissue by light energy emitted by carbon dioxide. (2) An argon laser for use in dermatology is a laser device intended to destroy or coagulate tissue by light energy emitted by argon.

(b) Classification. Class II.

Device Class: Class II for all requested indications
Classification Panel: General and Plastic Surgery & Others
Product Code(s): GEX

4. ***Section 514 Compliance***

TECHNOLOGY DELIVERY SYSTEMS, INC. intends to comply fully with the general controls authorized under Sections 501, 502, 510, 516, 518, 519, and 520 of the Food, Drug, and Cosmetic Act.

5. ***Performance Standards***

United States Food and Drug Administration mandated performance standards for this device exist and are provided under Sections 21 CFR 1010 & 1020. In addition, various voluntary performance standards are utilized. Voluntary standards utilized include Standard Operating Procedures, vendor & process certification and qualification procedures, Quality Systems Regulations, ISO materials standards and cGMP & ISO 9000 series quality regulations.

TECHNOLOGY DELIVERY SYSTEMS, INC. also meets appropriate general controls authorized under Sections 501, 502, 510, 516, 518, 519, and 520 of the Food, Drug, and Cosmetic Act.

6. ***Special Controls:***

All Class II devices are subject to Special Controls.

7. ***Labeling:***

The laser system discussed in this premarket notification will be manufactured by Technology Delivery Systems, Inc. and labeled as such. Technology Delivery Systems, Inc. will market the system exclusively to healthcare facilities, physicians and dentists. In addition to the usual package and identification

labeling, the following additional Warnings, Cautions & Precautions statements are displayed as appropriate on or within the device packaging. They are repeated here for ease of review.

Warning: Federal (United States) Law restricts this device to sale by or on the order of a physician or dentist only.

8. ***Summary Basis of Equivalence:***

The surgical laser fiber optic bundle described in this document is substantially equivalent to the referenced legally marketed laser system fiber optic bundles in that the sizes, operational parameters, indications for use, warnings, cautions, precautions and care and handling are essentially the same. The following comparison chart presents the features of all these fiber optic bundles.

9. ***Predicate Device*** *(legally marketed comparison devices)*

Technology Delivery Systems, Inc. believes that the following surgical laser fiber optic systems noted in the table are substantially equivalent to the **MaxiFlex - Fiberoptic Energy Delivery System**.

FEATURE	***MaxiFlex Fiberoptic Energy Delivery System***	StrateFire	InnovaQuartz	SE?
Type of laser	Diode & crystal fiber-optic based lasers	Any surgical laser equipment fitted with an SMA 905 connector	Nd:YAG, HO:YAG or Argon	YES
Wavelength	532-2100 nm	532-1400 nm	532-1054	YES
Max output power	100 Watts	100 Watts	60 Watts	YES
Operation mode	Continuous wave and pulsed	Continuous wave and pulsed	Continuous wave and pulsed	YES
Delivery system	Multi-mode 200, 400, 600 and 1000 um core quartz fiber	Multi-mode 400, 600, 800 and 1000 um core quartz fiber	Multi-mode 200, 400, 600 um core quartz fiber,	YES
Sterility:	User sterilized - Steam - 270° /10min. exposure	User sterilized - Steam - 270° /10min. exposure	User sterilized - Steam - 270° /10min. exposure	
Connector Type:	SMA 905 connector	SMA 905 connector	SMA 905 connector	YES
Intended Use and Indications for Use	The ***MaxiFlex - Fiberoptic Energy Delivery System*** is designed to deliver laser energy to perform: general surgical, dermatological, intraoral soft tissue, orthopaedic, maxillo-facial, and cosmetic surgery. The MaxiFlex fiber is intended for energy delivery for ablating, incising, excising, vaporization and coagulation of soft tissues within the medical/surgical specialties noted above using a contact fiber optic based laser system. The device is suitable for use for all applications for which the laser output unit is cleared, including: general and cosmetic surgery, intraoral soft-tissue, otolaryngology, arthroscopy, gastroenterology, general surgery, dermatology & plastic surgery, neurosurgery, gynecology, urology, ophthalmology and pulmonary surgery.	Ablation and hemostasis in treatment of gynecological and urological conditions, as well as multiple applications in gastroenterology and general surgery.	Vaporization, coagulation, hemostasis, and incision of soft-tissue. For use with Nd:YAG, HO:YAG or Argon laser systems cleared for medical use accepting an SMA 905 connector.	YES

10. Device Description:

The delivery fiber cables, consist of multi-mode, single core optical fibers available in 200, 400, 600 and 1000um diameters. The standard SMA 905 fiber connector terminates one end of the delivery fiber, which is attached to the SMA union at the rear panel of the laser box. The other end of the fiber is stripped of its protective jacket in accordance with the laser manufacturers instructions and is cleaved to provide laser radiation output.

11. Applicant Name & Address:

Technology Delivery Systems, Inc.
1354 Del Plaza, Suite 8
Baton Rouge, LA 70815
225.927.7885 - 225.926.2401

12. Company Contact:

Mr. Gary Ventrella
Technology Delivery Systems, Inc.
1354 Del Plaza, Suite 8
Baton Rouge, LA 70815
225.927.7885 - 225.926.2401

13. Submission Correspondent:

Mr. David W. Schlerf
Buckman Company, Inc.
200 Gregory Lane, Suite C -100
Pleasant Hill, CA 94523-3389
925.356.2640 - 925.356.2654 - fax

14. Manufacturing Facility:

The devices are physically manufactured in the USA by Technology Delivery Systems, Inc. for distribution in the U.S.A.

15. Sterilization, Packaging & Storage Information:

The device is not supplied sterile. All packages should be intact upon receipt. Packaging should be inspected on arrival for evidence of shipping damage. Damaged packaging may indicate the presence of unsafe product and it should not be used until carefully inspected. If the package or product is damaged, the product should not be used and should be returned. Product must be handled, stored and opened in such a way that it is protected from inadvertent damage or contamination. When used, the product must be placed into use following the recommended cleaning and sterilization procedure including accepted surgical sterile technique.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 6 2002

Technology Systems, Inc.
c/o Mr. David W. Schlerf
Buckman Company, Inc.
200 Gregory Lane, Suite C-100
Pleasant Hill, CA 94523-3389

Re: K013300
Trade/Device Name: MaxiFlex - Fiberoptic Energy Delivery System
Regulation Number: 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: March 5, 2002
Received: March 6, 2002

Dear Mr. Schlerf:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K013300

Device Name(s): ***MaxiFlex - Fiberoptic Energy Delivery System***

Intended Use(s) of the Device:

The ***MaxiFlex - Fiberoptic Energy Delivery System*** is designed to deliver laser energy to perform: general surgical, dermatological, intraoral soft tissue, orthopaedic, maxillo-facial, and cosmetic surgery. The MaxiFlex fiber is intended for energy delivery for ablating, incising, excising, vaporization and coagulation of soft tissues within the medical/surgical specialties noted above using a contact fiber optic based laser system.

The device is suitable for use for all applications for which the laser output unit is cleared, including: general and cosmetic surgery, intraoral soft-tissue, otolaryngology, arthroscopy, gastroenterology, general surgery, dermatology & plastic surgery, neurosurgery, gynecology, urology, ophthalmology and pulmonary surgery.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional format 1-2-96)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013300